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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,192	06/23/2006	Takayuki Oniki	0171-1287PUS1	3847
2292 7590 08/19/2009 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747				
EXAMINER				
SUTTON, DARRYL C				
ART UNIT		PAPER NUMBER		
1612				
NOTIFICATION DATE		DELIVERY MODE		
08/19/2009		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

### Office Action Summary

**Application No.**

10/584,192

**Applicant(s)**

ONIKI ET AL.

**Examiner**

DARRYL C. SUTTON

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 23-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 23-40 is/are rejected.
- 7) ☒ Claim(s) 23-40 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-893)  
Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/11/2009 has been entered.

Claims 1-22 have been canceled. New claims 23-40 have been added.

### ***Claim Objections***

Claims 23-40 are objected to because of the following informalities: In line 1 of each of claims 23 and 31, the term "reversible" should read "reversibly". There is a comma missing between the words "tape" and "sheet" in line 3 of claim 39. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 30 and 38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a new matter rejection.

The term "formed polyethylene" does not appear to be specifically disclosed anywhere in the specification as originally filed, insofar as the Examiner can determine. Accordingly, this appears to be new matter; Applicant is required to point out where the term allegedly finds original support.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 23-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "substantially free of water and peroxide" in claims 23, 31 and 39 is a relative term which renders the claim indefinite. The term "substantially free" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

The skilled artisan would not be able to ascertain the amount of water and peroxide that could be in the compositions in order for them to be considered "substantially free" of water and peroxide.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 23-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oniki et al. (WO 03/030851), US application 10/491191 provided as a translation, in view of Takeda et al. (US 2001/0007652).

Oniki et al. teach a method of making teeth look whiter by causing a whitening component to infiltrate into the tooth enamel, thereby changing the optical properties of the enamel without chemical reactions (page 1, lines 8-15, page 2, lines 33-37). The method reversibly makes teeth look apparently cloudy and whiter (page 3, lines 1-7). The whitening component is one or more selected from lower alcohols having four or less carbon atoms, such as ethanol, isopropyl alcohol, n-propanol and n-butanol; glycols having ten or less carbon atoms such as propylene glycol, diethylene glycol, ethylene glycol, dipropylene glycol and 1,3-butyleneglycol; polyethylene glycols, such as those having a molecular weight of 200-800; glycerin and diglycerin (page 4, lines 15-29). The whitening component can be used in conjunction with water in a ratio as high as 100/0, i.e.

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no water (page 5, lines 7-11). The amount of whitening component should preferably be 20% to 100% of the entire composition (page 5, lines 19-20). The tooth whitening composition is comprised of a gelling agent such as carboxymethylcellulose in amounts from 0.1 to 15% (page 6, lines 8-13). The whitening composition is incorporated with surfactants such as sodium lauryl sulfate in amounts from 0.1 to 10% (page 6, lines 27-31). The whitening composition should preferably be applied to teeth in concert with a special tool which retains and keeps it in position in contact with teeth, prevents the composition from dissolving and dilution by saliva and eliminates unpleasant feeling. It may be formed from a water-insoluble material in the form of a tape, sheet or film (page 8, lines 24-36). The tools should be formed from materials such as polyethylene, foamed polyethylene, polypropylene, polyester, rayon, pulp, cotton, silk and paper (page 9, lines 13-15). The duration of application is 1 to 120 minutes per dosage (page 10, lines 9-12).

Oniki et al. does not teach that the composition is further comprised of a substance (B).

Takeda et al. teach a dentifrice composition for imparting gloss on teeth comprising shellac; when the composition is used the whiteness inherent in teeth can be given to the teeth, and good gloss, brightness and luster can be further imparted on teeth due to the prevention of the irregular reflection of light by a coating of shellac (Abstract, [0039]), i.e. shellac changes the optical properties of teeth. The composition can be in the form of a gel [0007], [0016]. The content of shellac is 0.01% to 10% [0013]. The composition comprises propylene glycol

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and/or glycerin [0018]. Thickening agents such as sodium carboxymethylcellulose are used in the compositions [0017]. Foaming agents such as sodium lauryl sulfate may be included in the composition in amounts of 1.5% by weight [0017] and [0025]. No particular limitation is imposed on the usage of the dentifrice compositions [0019]. Shellac is comprised of jalaric acid and aleuritic acid, i.e.

9,10,16-trihydroxypalmitic acid with ester or lactone linkage.<sup>1</sup>

Takeda et al. does not teach a specific embodiment comprised as in claim 1.

Generally, it is *prima facie* obvious to combine two compositions, each of which is taught by the prior art to be useful for same purpose, in order to form a third composition to be used for the very same purpose. The idea for combining them flows logically from their having been individually taught in the prior art. See MPEP 2144.06. Accordingly, it would have been obvious to combine the shellac in the weight ratios of Takeda with the composition of Oniki et al. in order to form a third solution that also changes the optical properties of teeth and makes teeth appear white.

In regards to claims 28 and 36, the prior art does not teach the specific amounts of the tooth whitening ingredient, A. The prior art does not disclose the exact claimed values, but does overlap: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d

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<sup>1</sup> Sharma, S.K. et al., Shellac-Structure, Characteristics & Modifications, Def. Sci. J., 1983, p. 262-263.

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1379, 1382 (Fed. Cir. 2003). Oniki et al. teach from 20% to 100% of the whitening ingredient versus 50.0 to 99.5% of the instant claims.

All claims are rejected.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darryl C. Sutton whose telephone number is (571)270-3286. The examiner can normally be reached on M-Th from 7:30AM to 5:00PM EST or on Fr from 7:30AM to 4:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass, can be reached at (571)272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Darryl C Sutton/  
Examiner, Art Unit 1612

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612